

REMARKS

Claims 1-29 are pending and stand rejected. Applicants respectfully request reconsideration of the present application in view of the above amendments and following remarks.

Amendments to the Claims

Applicants amend independent claim 1 to recite that the cell growth conduit flap contacts a tibial surface and extends to the synovium. Applicants also amend independent claims 21 and 25 to include the features recited in claims 24 and 26. Support for these amendments can be found throughout the specification, for example, at Par. 0041 of the published application. Claims 3, 24, and 26 are cancelled. No new matter is added.

Rejections Pursuant to 35 U.S.C. §102

Malaviya '797

The Examiner rejects claims 1-8, 10-17, 20-21, 25, and 27 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Publication No. 2003/0036797 of Malaviya et al. ("Malaviya '797"). Applicants respectfully disagree.

Claim 1

As noted above, claim 1 is amended to recite a cell growth conduit flap contacting a tibial surface and extending to the synovium. Applicants submit that claim 1 distinguishes over Malaviya '797 and represents allowable subject matter. The Examiner asserts that Malaviya '797 "discloses that the cell growth conduit flap is adapted to contact the synovium, as it is capable of being placed next to the synovium." The Examiner states that "while Malaviya et al. says the surgeon will generally leave an outer rim (P0134), it does not state that they are required to leave an outer rim, and can thus be placed against the synovium." However, on page 7 of the Office Action the Examiner admits that "Malaviya ['797] does not explicitly disclose that the cell growth conduit flap is in contact with the synovium." Indeed, Malaviya '797 does not teach or suggest a cell growth conduit flap that contacts a tibial surface and *extends to the synovium*. Malaviya '797 teaches that "the device is shaped to conform to the space into which it is inserted such that the surrounding tissue of the remaining meniscus is in contact with the device." (Malaviya '797 at Par. 0018.) Malaviya '797 also teaches that "regeneration is encouraged by

structuring the device such that the vascular rich portion of the original meniscus and the adjacent radially outer portion of the original meniscus will work with the device and particularly the mass of biological material under the upper cover of the device to regenerate the meniscal tissue.” (Malaviya ‘797 at Par. 0024.) Thus, Malaviya ‘797 teaches that the “adjacent radially outer portion of the original meniscus” is retained and contacts the device. The radially outer portion of the original meniscus prevents the device from extending to the synovium as required by claim 1. As such, Malaviya ‘797 not only does not anticipate claim 1, but effectively teaches away from the instant invention.

Accordingly, independent claim 1 distinguishes over Malaviya ‘797 and represents allowable subject matter. Claims 2 and 4-20 likewise distinguish over Malaviya ‘797 by virtue of their dependence on claim 1.

Claims 21 and 25

Claims 21 and 25 are amended to recite positioning the cell growth conduit flap in contact with the synovium. Applicants submit that claims 21 and 25 distinguish over Malaviya ‘797 and represent allowable subject matter. Malaviya ‘797 does not teach or suggest positioning a cell growth conduit flap in contact with the synovium. Indeed, on page 7 of the Office Action the Examiner admits that “Malaviya [‘797] does not explicitly disclose that the cell growth conduit flap is in contact with the synovium.” As discussed above with respect to claim 1, Malaviya ‘797 teaches that the “adjacent radially outer portion of the original meniscus” is retained and contacts the device. (See Malaviya ‘797 at Par. 0024.) Also as discussed above, the retained radially outer portion of the original meniscus prevents the device from being positioned in contact with the synovium, as required by claims 21 and 25.

Accordingly, independent claims 21 and 25 distinguish over Malaviya ‘797 and represent allowable subject matter. Claims 22-23 and 27-29 depend from claims 21 and 25, respectively and therefore distinguish over Malaviya ‘797 for all the reasons discussed with respect to claims 21 or 25.

Malaviya ‘344

The Examiner rejects claims 1 and 18 pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Publication No. 2004/0143344 of Malaviya et al. (“Malaviya ‘344”). Applicants respectfully disagree. As discussed above, claim 1 recites a cell growth conduit flap contacting a tibial surface and extending to the synovium. Applicants submit that claim 1 distinguishes over

Malaviya '344 and represents allowable subject matter. As discussed above, on page 7 of the Office Action the Examiner admits that "Malaviya ['797] does not explicitly disclose that the cell growth conduit flap is in contact with the synovium." Like Malaviya '797, from which it is a continuation-in-part, Malaviya '344 does not teach or suggest a cell growth conduit flap that contacts a tibial surface and *extends to the synovium*. As shown in FIG. 8, the outer portion of the meniscus is retained. Malaviya '344 teaches that device 10 is implanted in a meniscus "with sutures 30 affixing the device 10 to the native meniscus 28." (Malaviya '344 at Par. 0045 and FIG. 8.) Applicants note that although FIG. 8A shows a "wing" of the implant extending beyond the edge of the meniscus, Malaviya '344 teaches only that the "wing" can be used to "fix the implant directly to the patient's tibia 70, for example by inserting a screw 72 through the wing 25 and into the tibia 70." (Malaviya '344 at Par. 0073.) There is no teaching or suggestion that the wing extends to the synovium or that the wing is adapted to communicate biological materials to the tissue defect in the meniscus, as required by claim 1.

Accordingly, independent claim 1 distinguishes over Malaviya '344 and represents allowable subject matter. Claim 18 depends from claim 1 and therefore distinguishes over Malaviya '344 for all the reasons discussed with respect to claim 1.

Rejections Pursuant to 35 U.S.C. §103

Malaviya '797

The Examiner rejects claims 9, 24, and 26 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya '797. Applicants respectfully disagree with the Examiner's rejection.

At the outset, Applicants note that claim 9 depends from claim 1 and therefore distinguishes over Malaviya '797 for all the reasons discussed above with respect to claim 1. In brief, Malaviya '797 neither teaches nor suggests a cell growth conduit flap that contacts a tibial surface and extends to the synovium because the radially outer portion of the original meniscus prevents the device from extending to the synovium as required by claim 1.

As discussed above, claims 24 and 26 have been cancelled. However, claims 21 and 25 are amended to include the features recited therein. As amended, claims 21 and 25 recite that the cell growth conduit flap is positioned in contact with a tibial surface and the synovium. The Examiner admits that "Malaviya does not explicitly disclose that the cell growth conduit flap is in contact with the synovium." The Examiner asserts that Malaviya '797 states that "one or more of the layers of the material forming the upper cover or the lower cover may be formed to provide

tabs extending away from the device to facilitate attachment to the surrounding tissue.” The Examiner then argues that the tabs “could extend to the synovium.” However, claims 21 and 25 also recite that “the cell growth conduit flap allows cells and nutrients to travel to the defect in the meniscus.” Malaviya ‘797 teaches only that the tabs are fastened to surrounding tissue. (See Malaviya ‘797 at Par. 0169- 0170.) There is no teaching or suggestion in Malaviya ‘797 that the tabs allow cells and nutrients to travel to the defect in the meniscus. Malaviya ‘797 also discloses that “if the knee is sufficiently immobilized for a period of time subsequent to implantation to keep upper cover 161 and lower cover 163 apart, blood and synovial fluid will infiltrate open space 165.” (Malaviya ‘797 at Par. 0153.) However, there is no teaching or suggestion that the tabs, or any other portion of the device allow “blood and synovial fluid” to “infiltrate the open space.” Malaviya ‘797 teaches “channeling blood flow from the vascular rich outer portion of the meniscus to the radially inner portion of the device.” (Malaviya ‘797 at Par. 024.) There is, however, no teaching or suggestion that the tabs, which are only taught as a fastening element, allow the blood or synovial fluid to travel to the inner portion of the device. Therefore, there is no teaching or suggestion in Malaviya ‘797 that the tab extensions, or any other part of the implant, are in contact with the synovium or allow cells and nutrients to travel to the defect in the meniscus. Furthermore, as discussed above, Malaviya ‘797 teaches that the “adjacent radially outer portion of the original meniscus” is retained and contacts the device. The radially outer portion of the original meniscus thus prevents the device from extending to the synovium. As such, Malaviya ‘797 not only does not teach or suggest the features recited in claims 21 and 25, but effectively teaches away from the instant invention.

Malaviya ‘797 in view of Li

The Examiner rejects claims 22, 23, 28, and 29 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya ‘797 in view of US Patent No. 4,790,819 of Li et al. (“Li”). Applicants respectfully disagree.

Claims 22-23 and claims 28-29 depend from claims 21 and 25, respectively, and therefore distinguish over Malaviya ‘797 for all the reasons discussed above with respect to claims 21 and 25. The Examiner admits that Malaviya ‘797 does not disclose the rasping step recited in claims 22 and 23. The Examiner relies on Li to teach the rasping step. Although Li teaches “using an arthroscopy rasp to abrade the superior and inferior parameniscal synovium,” Li does not remedy the deficiencies of Malaviya ‘797 with respect to the features recited in claim 21 and 25 from which claims 22-23 and 28-29 depend. (See Li at Col. 1, lines 27-31).

Li discloses “a delivery device for depositing an exogenous fibrin clot into a wound site during an arthroscopic surgical operation.” (Li at Abstract). As discussed above, claims 21 and 25, as amended, recite positioning the cell growth conduit flap in contact with the synovium. In the background of the invention, Li discloses “using an arthroscopy rasp to abrade the superior and inferior parameniscal synovium to increase blood supply to the meniscal tear.” (Li at Col. 1, lines 27-31). However, Li does not teach or suggest depositing the fibrin clot material in contact with the synovium. Li merely discloses injecting “a quantity of fibrin clot material into the meniscle tear within the wound site.” (Li at Col. 6, lines 63-65). In addition, Li does not disclose using the rasping step in combination with depositing the fibrin clot material. Indeed, Li’s invention represents an improvement to methods that require rasping the synovium to create a fibrin clot. Regardless, Li fails to remedy the deficiencies of Malaviya ‘797 because Li fails to teach or suggest that the fibrin clot material is placed in contact with the synovium. Claims 22, 23, 28, and 29 therefore distinguish over Malaviya ‘797 and Li and represent allowable subject matter.

Malaviya ‘344 in view of Malaviya ‘444

The Examiner rejects claim 19 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya ‘344 in view of US Patent Publication No. 2003/0044444 of Malaviya et al. (“Malaviya ‘444”). Applicants respectfully disagree.

Dependent claim 19 recites that “the density of the cell growth conduit flap is in the range of about 150 mg/cc to 350 mg/cc.” The Examiner admits that Malaviya ‘344 “does not disclose that the density is in the range of about 150-350 mg/cc.” The Examiner relies on Malaviya ‘444 to teach that “an ECM scaffold can be made to have a desired density.” Although Malaviya ‘444 teaches the steps of “fabricating a porous scaffold with a desired pore size and density,” Malaviya ‘444 fails to teach or suggest the claimed density range. Moreover, Malaviya ‘444 does not remedy the deficiencies of Malaviya ‘344 with respect to the features recited in independent claim 1, from which claim 19 depends. Malaviya ‘444 teaches a porous implantable scaffold, but fails to teach a cell growth conduit flap attached to a tissue repair scaffold. Consequently, the combination of Malaviya ‘344 and Malaviya ‘444 fails to teach a cell growth conduit flap that extends to the synovium that can communicate biological materials to a tissue defect in the meniscus. Claim 19 therefore distinguishes over Malaviya ‘344 and Malaviya ‘444 and represents allowable subject matter.

Conclusion

Applicants submit that all pending claims are allowable, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed necessary to expedite prosecution of this application.

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Respectfully submitted,

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